DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administrati n
Rockville MD 20857

FEB 24 2006

Re: S8 Over-the-Wire System
Docket Nos. 2004E-0300, 2004E-0301,
2004E-0302, 2004E-0303, 2004E-0304,
2004E-0306, and 2004E-0426

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,800,509; 5,891,190; 6,309,402; 5,879,382; 5,292,331; 5,836,965 and 6,344,053 filed by Medtronic Vascular under 35 U.S.C. § 156. The medical device claimed by these patents is S8 Over-the-Wire System, which was assigned PMA No. P030009.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The PMA was approved on October 1, 2003, which makes the submission of the patent term extension application on November 26, 2003, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research